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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,923	06/19/2000	NORMAN BRYSON ROBERTS	PM266300	3694

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PILLSBURY WINTHROP, LLP  
P.O. BOX 10500  
MCLEAN, VA 22102

EXAMINER
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VANOY, TIMOTHY C

ART UNIT	PAPER NUMBER
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1754

DATE MAILED: 06/24/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09-508,923

Applicant(s)  
ROBERTS et al.

Examiner  
VANDY

Group Art Unit  
1754

— The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- THE AMENDMENT DATED JAN. 22, 2002.
- ☒ Responsive to communication(s) filed on \_\_\_\_\_
- ☒ This action is FINAL. THE AMENDMENT DATED MAY 23, 2002 HAS BEEN ENTERED.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 15-23 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 15-23 is/are rejected.
- ☒ Claim(s) 15, 16, 19 AND 23 is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement

## Application Papers

- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☒ The drawing(s) filed on 06/19/00 is/are objected to by the Examiner
- ☐ The specification is objected to by the Examiner.
- ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☒ All ☐ Some ☐ None of the:
- ☒ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
- ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

Art Unit: 1754

## **DETAILED ACTION**

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Information Disclosure Statement***

a) *On pg. 7 in the Amendment dated Jan. 22, 2002 (paper no. 7), the Applicants comment that a new IDS is being filed concurrently herewith in order to submit and have made of record the documents mentioned in the specification. In addition, a partial English translation of JP 05 155776 is provided.*

The Applicants are advised that neither this IDS or the partial English translation of JP 05 155776 are present in this Application file.

### ***Oath/Declaration***

*Keep* The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because it does not identify the **city** and state or foreign country for the residence of the inventor "Mr. Norman Bryson Roberts" or the inventor "Mr. Maurice Webb".

*The Applicants comment that GB is identified on the address line for Mr. Roberts and Mr. Webb and "United Kingdom" is provided in the space for the residence as a*

Art Unit: 1754

*continuation of the Full Post Office Address, the residence being the same in each instance.*

A new oath is required because address information has been provided on the "Residence" line of the oath and the oath indicates that address information is provided on this "Residence" line *if* the address information is different from that of the P. O. Box information. Therefore, by definition and instruction in the oath, the residence address and post office address for Mr. Roberts and Mr. Webb can not be the same.

### **Drawings**

- 31<sup>c</sup> a) Fig. 1 is objected to because it only illustrates seven sets of plotted data points (i. e. 7 lines) for eight different sets of data (i. e. 8 symbols).

*The Applicants comment that according to pg. 11 Ins. 14-16 in the Applicants' specification, the data points for the "Ca:Fe 3:1 unaged" are masked beneath the data points for the "Ca:Fe 3:1 aged" (, therefore the 8<sup>th</sup> data set is actually illustrated).*

In view of the Applicants' comments it is suggested to change the data point geometry representing the "Ca:Fe 3:1 unaged" to a shape that is different from the geometry of the data point representing the "Ca:Fe 3:1 aged" (such as an oval-shaped data point), rather than canceling the reference to "Ca:Fe 3:1 unaged" from Fig. 1.

### **Claim Objections**

- Keep  
a) Claim 16 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of previous claim 15 in as much as

Art Unit: 1754

claim 16 broadens the pH range of claim 15 from a pH of 3 to 7 to a pH of 2 to 8. The Applicants are required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

of b) The incorporation by reference of the test methods 1, 2 and 3 described in the Applicants' specification into claims 15, 19 and 23 is objected to in view of the discussion of the *Ex Parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) court decision set forth in section 2173.05(s) in the MPEP (8<sup>th</sup> ed.). While it is granted that this section of the MPEP is directed to incorporating by reference figures and tables into the claim language, it appears that the same principles would be equally applicable to incorporating by reference test methods described in the Applicants' specification.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

of Claims 22, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by U. S. Pat. 5,173,284.

Examples 5 and 6 in U. S. Pat. 5,173,284 disclose a method for recrystallizing calcium sulfate dihydrate by providing a solution of calcium sulfate and adding sodium

Art Unit: 1754

hydroxide to the solution of calcium sulfate. The resulting solution was seeded with gypsum primers to produce dehydrated calcium sulfate crystals.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The person "having ordinary skill in the art" has the capability of understanding the scientific and engineering principles applicable to the claimed invention. The references of record in this application reasonably reflect this level of skill.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

Art Unit: 1754

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Japan Pat. Doc. No. 5-155,776 A in view of German Pat. Doc. No. 34 02 878 A1 to Dietl.

The English abstract of JP-776 discloses a method for treating hyperphosphatemia by administering a drug/medicament to the patient. The drug/medicament may be in the form of a tablet and contains  $\text{Fe}(\text{OH})_3$  as the active ingredient. From the information set forth in paragraph no. [0020] in col. 4 in the text of JP-776, it appears that the  $\text{Fe}(\text{OH})_3$  was made by mixing  $\text{FeCl}_3$  with 1 molar solution of  $\text{NaOH}$  and precipitating out of the  $\text{Fe}(\text{OH})_3$ .

Note that Figs. 1 and 2 in JP-776 appear to suggest/disclose that the drug is active at pH values ranging from 2 to 8, in a manner that is not seen to be distinct from the pH limitations in the Applicants' claims.

The difference between the Applicants' claims and JP-776 is that the Applicants' claims call for the use of a mixed metal compound (*whereas JP-776 only uses  $\text{Fe}(\text{OH})_3$* ) which was obtained by forming a precipitate from a solution of a mixture of metal salts (*whereas JP-776 only appears to form a precipitate from a solution of a single metal salt ( $\text{FeCl}_3$ )*) wherein the precipitate contains iron(III) and at least one of magnesium, calcium, lanthanum and cerium (*whereas JP-776 only reports the presence of their iron(III) compound*).

The English abstract of DE-878 reports the use of a drug comprising compounds, such as  $\text{CaCO}_3$ ,  $\text{Ca(OH)}_2$ ,  $\text{CaO}$  and/or  $\text{CaSO}_4$  which act to bind the phosphate, to treat hyperphosphatemia.

It would have been obvious to one of ordinary skill in the art at the time the invention was made *to modify* the process and composition of JP-776 *by including* the  $\text{CaSO}_4$ , etc. . . disclosed in the English abstract of DE-878, *in the manner required by* the Applicants' claims *because* the English abstract of DE-878 discloses that the  $\text{CaSO}_4$ , etc. . . are phosphate binders in drugs used to treat hyperphosphatemia (the same field of endeavor as JP-776 and the Applicants' claims) and the courts have already determined that "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . [T]he idea of combining them flows logically from their having been individually taught in the prior art.": please note the discussion of the *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) court decision discussed in section 2144.06 in the MPEP (Aug. 2001).

~~81~~ Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over U. S. Pat. 5,173,284.

Claims 22, 24 and 25 are submitted to be obvious from U. S. Pat. 5,173,284 for the reasons set forth in the 102 rejection of claims 22, 24 and 25, consistent with the conclusion set forth in *In re Kalm* 154 USPQ 10 where it was determined that anticipation is the epitome of obviousness.



The difference between the Applicants' claims and U. S. Pat. 5,173,284 is that Applicants' claim 23 describes the capacity of the calcium sulfate to bind phosphate at a capacity of at least 30% according to tests 1, 2 or 3 set forth in the Applicants' specification, *however* it is submitted that this difference would have been obvious to one of ordinary skill in the art at the time the invention was made *because* the courts have already determined that such recognition of latent properties in the prior art does not render nonobvious an otherwise known invention: please see the discussion of the *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979) court decision set forth in section 2145(II) in the MPEP (8<sup>th</sup> ed.).

### ***Response to Arguments***

The Applicants' arguments submitted in their Amendment dated Jan. 22, 2002 (paper no. 7) have been fully considered but they are not persuasive.

a) *The Applicants argue that the compound of JP-776 is a mixture of metal compounds, whereas the present claims are directed to metal compounds (compounds having 2 or more metals as in a hydrotalcite).*

The scope of the "solid mixed metal compound" set forth in Applicants' independent claims 15, 19 and 20 and the "solid metal sulfate material"/"solid material" of Applicants' claims 21, 22 and 24 are broad enough to embrace the compound resulting from the inclusion of the CaSO<sub>4</sub>, etc. of DE 34 02 878 A1 into the aqueous solution containing FeCl<sub>3</sub> and NaOH which appears to be disclosed in paragraph no. [0020] in the text of JP-776. None of the claims are limited to the argued "hydrotalcite".

Art Unit: 1754

The metal sulfate material of Applicants' claims 21-25 would not be a "hydrotalcite" ( $\text{Mg}_6\text{Al}_2(\text{CO}_3)(\text{OH})_{16} \cdot 4\text{H}_2\text{O}$ ). It appears that the composition resulting from the addition of the  $\text{CaSO}_4$  of DE-878 into the aqueous solution comprising alkali metal hydroxide taught in JP-776 would be the same "mixed metal compound" of at least Applicants' claim 15.

b) *The Applicants argue that Fig. 1 illustrated in JP-776 does not show the compounds to be effective over a pH range of 3 to 7 or from 2 to 8.*

Fig. 1 appears to illustrate the removal of phosphate values at a pH as high as 8 using their compounds. The addition of the  $\text{CaSO}_4$ , etc. from DE-878 into the composition of JP-776 is expected to synergistically enhance effectiveness of the composition of JP-776 in removing phosphate: consistent with the discussion of the *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) court decision discussed in section 2144.06 in the MPEP (Aug. 2001).

c) *The Applicants argue that from the information provided in paragraph numbers [0022] and [0024] in JP-776, the best absorbance over the pH range of 4 to 8 would only be about 10% (rather than the claimed 30%).*

The Applicants' claims are not limited to treatment at a minimum pH of 4, but embrace treatment at pHs as low as 2 illustrated in figures of JP-776.

In response to the Applicants' arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208

Art Unit: 1754

USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

While that it is granted that the exact phosphate binding capacity for the compound resulting from the inclusion of the  $\text{CaSO}_4$ , etc. of DE-878 into the composition of JP776 in the manner set forth in the "at least 30% absorption efficiency" limitation set forth in the Applicants' claims would not be predictable from the information provided in JP-776 and DE-878, obviousness does not require such *absolute* predictability: please see the discussion of the *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) court decision set forth in section 2143.02 in the MPEP (8<sup>th</sup> ed.).

d) *The Applicants argue that given the known limitations of calcium compounds and their rather poor solubility at pH of 6 to 9, it is highly unlikely that the skilled practitioner would have been motivated to use the combination of the teachings of JP-776 and DE-878.*

The solubility characteristics of the iron/calcium compounds of Applicants' claims 15-20 and the composition resulting from the combination of JP-776 and DE-878 are expected to be distinct from the argued solubility characteristics of  $\text{CaSO}_4$ , per se.

In view of the discussion of the court decisions set forth in section 2144.06 in the MPEP (8<sup>th</sup> ed.), it appears that the known use of the  $\text{CaSO}_4$ , etc. of DE-878 as a phosphate binder is sufficient motivation in and of its self to combine it with the known and conventional phosphate binder of JP-776 only to achieve the expected advantage

Art Unit: 1754

of obtaining a third composition also useful for the same purpose of binding phosphate – as disclosed in JP-776 and DE-878.

e) *The Applicants argue that if JP-776 and DE-878 were combined, one of ordinary skill in the art would not be able to predict the properties (of the compound resulting from the combination of JP-776 and DE-878: i. e. the phosphate binding capacity being at least 30% over a pH of 2 to 8).*

In view of the discussion of the court decisions set forth in section 2145(II) in the MPEP (8<sup>th</sup> ed.), it would not seem that one of ordinary skill in the art would have to be able to predict the “inherent property” of the resulting composition exhibiting a phosphate binding capacity of at least 30% over a pH of 2 to 8 in order to establish a case of *prima facie* obviousness – in the manner that the Applicants' argument seems to suggest.

f) *The Applicants argue that combining the disclosures of JP-776 and DE-878 would result in only mixtures of e. g. iron hydroxide and calcium or magnesium carbonate, not a mixed metal compound as claimed herein. One skilled in the art would not be able to predict the properties of the resulting compound based on the properties of the properties of the individual compounds.*

There is no evidence of record establishing that the compound resulting from the combination of JP-776 and DE-878 would only be a mixture of metal compounds, rather than a mixed metal compound as the Applicants' argue: please see the discussion of the court decisions set forth in section 2145(I) in the MPEP (8<sup>th</sup> ed.) for further details. Also, in view of the logic of the Applicants' argument, it can not be predicted with

Art Unit: 1754

certainty that the composition resulting from the combination of JP-776 and DE-878 would inherently have a phosphate binding efficiency that is *outside* the claimed at least 30% over a pH range of 2 to 8 simply because JP-776 discloses poorer binding efficiencies at a pH of 4 to 8 as compared to the binding efficiency at a pH of 2 to 3 and also because certain calcium compounds of DE-878 may have poor solubilities at a pH of 6 to 9.

Absolute predictability is not required to establish a case of prima facie obviousness: please see the discussion of the *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) court decision set forth in section 2143.02 in the MPEP (8<sup>th</sup> ed.).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1754

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy C. Vanoy whose telephone number is 703-308-2540. The examiner can normally be reached on 8 hr. days.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stanley Silverman, can be reached on 703-308-3837. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Timothy Vanoy  
June 18, 2002

  
Timothy Vanoy  
Patent Examiner

Art Unit 1754